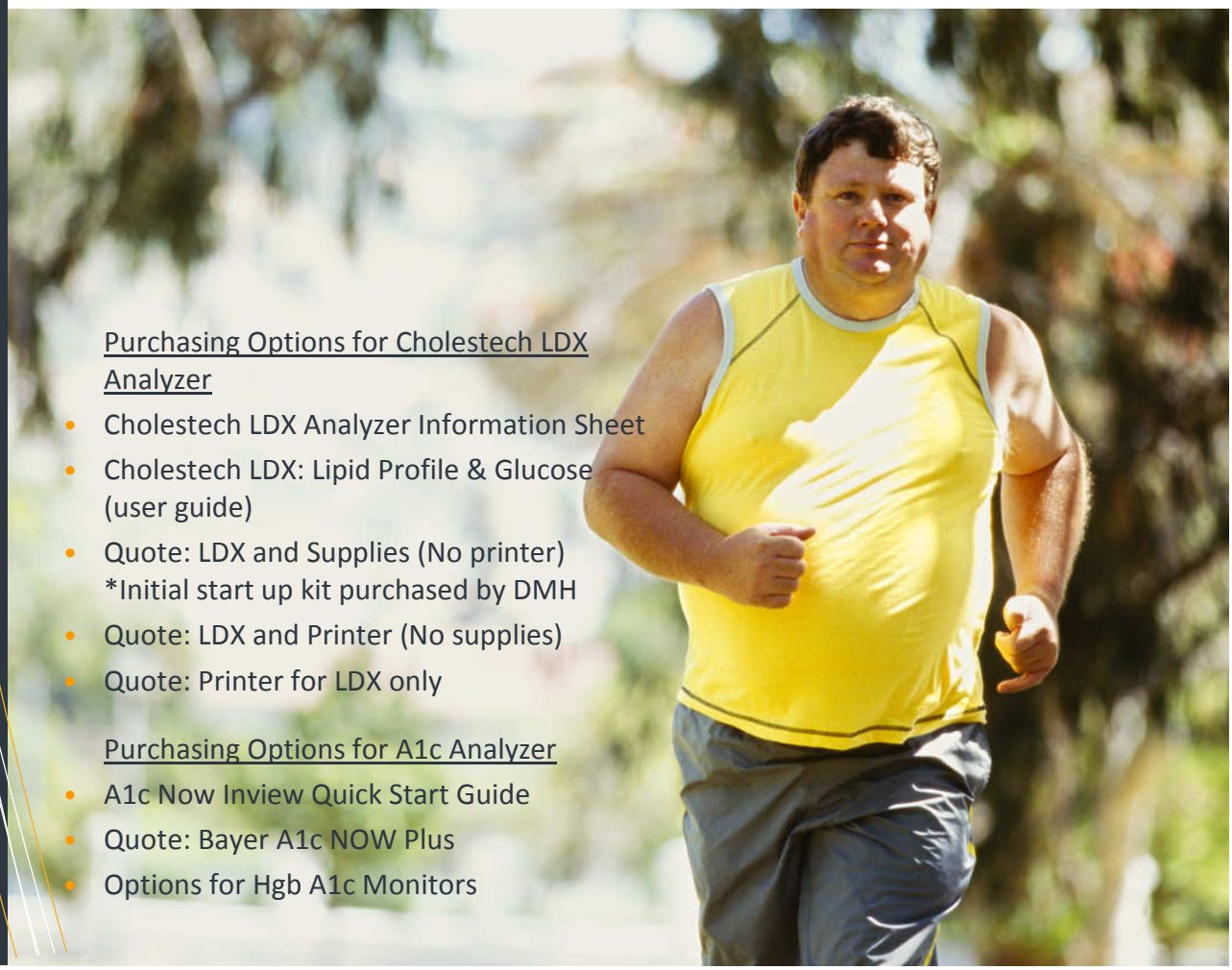
Missouri
DMH Net
DISEASE MANAGEMENT INITIATIVE

Metabolic Syndrome

PURCHASING OPTIONS FOR LDX AND A1C ANALYZERS



Purchasing Options for Cholestech LDX Analyzer

- Cholestech LDX Analyzer Information Sheet
- Cholestech LDX: Lipid Profile & Glucose (user guide)
- Quote: LDX and Supplies (No printer) *Initial start up kit purchased by DMH
- Quote: LDX and Printer (No supplies)
- Quote: Printer for LDX only

Purchasing Options for A1c Analyzer

- A1c Now Inview Quick Start Guide
- Quote: Bayer A1c NOW Plus
- Options for Hgb A1c Monitors

CHOLESTECH LDX® SYSTEM

http://www.cholestech.com/products/ldx_overview.htm

LDX SYSTEM TESTS »

- Lipid Profile•GLU
- Lipid Profile
- ALT•AST »
- hs-CRP »
- TC•HDL•GLU
- TC•HDL
- TC•GLU
- TC

The Cholestech LDX System brings a wealth of benefits to healthcare professionals and patients. The LDX System delivers the ability to measure a complete lipid profile and glucose, ALT, AST, and hs-CRP and it does it all in 5 minutes per test cassette (7 minutes for hs-CRP).

The accuracy, speed and broad menu of tests available for the Cholestech LDX make it an invaluable tool in the fight against heart disease, diabetes and metabolic syndrome. Best of all, the rapid results allow for immediate testing, counseling and treatment decisions.

Key Features

- Lab-accurate quality
  - Meets all relevant National Cholesterol Education Program (NCEP) guidelines
  - Certified for total and HDL cholesterol by the CDC's Cholesterol Reference Method Laboratory Network
- Immediate feedback for on-the-spot care decisions
- CLIA-waived*
- Tests require only a simple fingerstick
- Fast, easy 3-step procedure
- CHD risk assessment
- Easy and inexpensive software upgrades for new tests
- Small, lightweight design for versatility and portability (21cm x 12cm or 8¼" x 4¾")
- System includes an easy-to-use printer, providing multiple copies of results
- Tests reimbursable by Medicare and various private payors.

Cholestech LDX: Lipid Profile and Glucose

I. Purpose:

<NOTE: The Cholestech LDX is capable of performing multiple analytes – total cholesterol, HDL, triglycerides and glucose. Not all laboratories perform each of these tests. Your laboratory must therefore customize this procedure so that it accurately reflects the testing you actually perform. Instructions are provided in bold which indicate those areas that must be customized. Non-applicable items are to be deleted. Instructions (such as this one) are to be deleted before the procedure is printed and sent to the lab director for review and signature>

The Cholestech LDX is used for the quantitative determination of total cholesterol, HDL (high-density lipoprotein) cholesterol, triglycerides and glucose in whole blood. These analytes are measured simultaneously from a single drop of blood using the Cholestech LDX Analyzer. A TC/HDL (total cholesterol/HDL cholesterol) ratio and estimated values for LDL (low-density lipoprotein) and non-HDL cholesterol are calculated by the Cholestech LDX upon completion of testing. <**The laboratory must delete those analytes which are not tested for or documented>**

The Cholestech LDX System is CLIA-waived for fingerstick or venous whole blood unprocessed samples only. If serum or plasma is run on the Cholestech LDX, you will be classified as moderately complex and will have to comply with the regulations for moderate complexity.

II. Specimen:

A. Samples used for testing is whole blood from a fingerstick (collected in a lithium heparin-coated capillary tube. The sample is applied to a Cholestech LDX cassette.
B. When testing triglycerides or glucose, the subject should fast for 9-12 hours before the sample is collected.
C. Collect the sample from a fingerstick into a Cholestech LDX Capillary Tube. (See the Fingerstick Procedure later in this procedure.)
D. Place the blood into the cassette within 8 minutes of collection.
E. Blood from the fingerstick should flow freely. Too much squeezing of the finger may cause poor results.

III. Safety:

A. Gloves, eye protection, and laboratory coats must be worn whenever collecting fingerstick blood or whenever working with samples that are potentially biohazardous.
B. All laboratory staff must be familiar with the bloodborne pathogen and chemical hygiene plans of the laboratory.

C. All blood samples and containers, capillary tubes and materials that have come in contact with blood should be handled as if capable of transmitting infectious disease and discarded into a biohazard waste container after use.

IV. Materials

A. Instrumentation
1. Cholestech LDX Analyzer
2. Cholestech Printer, one each
3. Cholestech Power Supplies, 9 VDC
4. User Manual

B. Reagents and Standards
1. LDX System Test Cassettes <**The laboratory must customize this list by identifying the test system used in their laboratory and deleting the others>**
   a. Lipid Profile-Glucose, catalog number 10-991
      Total cholesterol, HDL cholesterol, non-HDL cholesterol, Triglycerides, LDL cholesterol, TC/HDL ratio, and glucose
   b. Lipid Profile, catalog number 10-989
      Total cholesterol, HDL cholesterol, non-HDL cholesterol, Triglycerides, LDL cholesterol, TC/HDL ratio
   c. TC-HDL-Glucose panel, catalog number 10-990
      Total cholesterol, HDL cholesterol, non-HDL cholesterol, TC/HDL ration, and glucose
   d. TC-HDL panel, catalog number 10-987
      Total cholesterol, HDL cholesterol, non-HDL cholesterol, and TC/HDL ratio
   e. TC-Glucose panel, catalog number 10-988
      Total cholesterol and glucose
   f. Total cholesterol, catalog 10-986
2. LDX Control Reagents <**The laboratory must customize this list by identifying the control used in their laboratory and deleting the others>**
   a. Lipid Controls (Lipids/glucose), catalog number 10-982
      Contains 1 vial of Level 1 control and 1 vial of Level 2 control, 2 mL per vial
   b. Lipid Controls (Lipids/glucose), catalog number 10-983
      Contains 3 vials of Level 1 control and 3 vials of Level 2 control, 2 mL per vial.
3. Calibration Reagents
   a. Optics check cassette with case, catalog number 10-228
   b. Calibration verification material, catalog number 11-255,
      Contains 1 vial each of Levels 1-4, 2 mL per vial

C. Supplies
1. Capillary tubes, Cholestech catalog 10-940. For use with all lipid and

glucose cassettes. For use with whole blood collected by fingerstick.
2. Capillary plungers, Cholestech catalog number 10-311. For use with the Cholestech capillary tubes.
3. Lancets, capable of 1.8 mm deep puncture
4. Alcohol swabs
5. Gloves
6. Gauze
7. Biohazardous waste container

D. Storage conditions - Controls
1. High and Low level whole blood controls; store at 2-8^{0}C, warm to room temperature for 15 minutes before use. Mix thoroughly by gentle inversion, DO NOT SHAKE.

E. Storage conditions - Cassette**s**
1. Cassettes **must** be stored in the sealed foil pouches.
2. Place cassettes in the refrigerator after receipt. Cassettes may be used until the date printed on the pouch when stored in a refrigerator (36–46°F / 2–8°C).
3. Alternatively, the cassettes may be stored for up to 30 days at room temperature (48–86°F / 9–30°C). The new expiration date is the date the cassettes are placed at room temperature plus 30 days. Write the new expiration date on the side of the cassette box in the space provided.
   • Once cassettes have been stored at room temperature, they should not be returned to the refrigerator.
   • Do not use a cassette that has been stored at room temperature for more than 30 days.
   • Do not use a cassette beyond the printed expiration date.
   • Do not reuse cassettes.

F. Cassette handling conditions
1. If cassettes are stored refrigerated, they should sit at room temperature for 10 minutes before opening the pouch.
2. Use the cassette as soon as the pouch is opened.

G. Operating conditions. The Cholestech LDX system must be used in a location:
1. That maintains a constant room temperature of 68-87^{o}F (20-31 ^{o}C),
2. That provides a stable work surface (i.e., no centrifuges are to used at the same time),
3. Not in direct heat (oven or room heater),
4. Not in bright light (sunlight or spotlight).

V. Quality Control

A. Controls

There are two control solutions available through Cholestech, a high level and low level. Controls are provided in sets of either 1 or 3 vials (2 mL per vial) of each control. Each set contains a package insert which states the specified mean and acceptable range for both the high and low level controls. These controls are recommended by the manufacturer for use with the Cholestech LDX system.

Alternatively, laboratories may use controls other than those available through Cholestech. If this is done, the laboratory must determine the precision and expected ranges on the Cholestech LDX System before patient testing is performed. **<This paragraph is to be deleted if the lab uses controls from Cholestech>**

B. Handling Controls
   1. Read the product insert that comes with each box of controls to find out how to use and store them.
   2. Check the expiration date before using. **Do not use expired control material.**
   3. Mix controls well before use. Hold the top and bottom of the bottle and gently turn it upside down seven to eight times to mix.
   4. Check the control assay sheet for the correct sample setting for running controls.
   5. Verify that the lot number on the control vial and the assay sheet are the same.

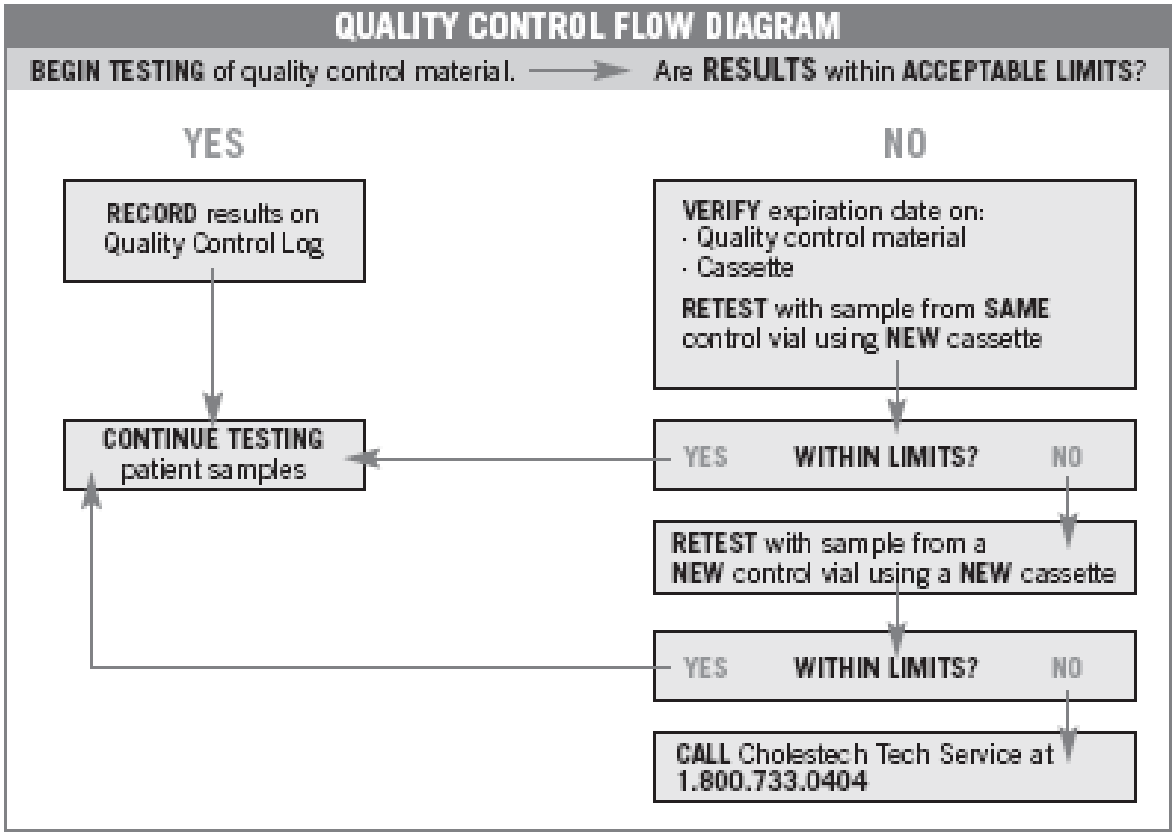
C. Frequency of controls. Controls must be tested:
   1. On a weekly basis (Monday – Friday) before any patient testing is performed.
   2. With each new shipment of cassettes (even if cassettes are from the same lot previously received).
   3. With each new lot of cassettes.
   4. Whenever there is any concern about test system integrity or operator technique (e.g., when reagents may have been stored or handled in a way that can degrade their performance or when operators have not performed a particular test in recent weeks).

D. Evaluation of control results
   1. Results within control range: If results for all analytes are within the expected ranges included with the control, patient samples may be tested and results reported.
   2. Results outside control range: If the controls fall outside the expected ranges included with the control, corrective action must be taken and the cause of the problem identified. Only after the problem has been corrected and control results are within the control range may patient samples be tested and results reported.

E. Frequency of Cholestech LDX optics check. Run the optics check cassette:

1. Once each day before patient samples are tested.
2. After the Cholestech LDX System has been moved or serviced.

F. Corrective Action
   1. Actions to be taken and documented whenever results of one or both levels of control tested are outside the established acceptable ranges:
      a. Verify that the lot number on the control and the assay sheet are the same.
      b. Check the expiration date for the test cassette and quality control materials. Discard expired products.
      c. Retest the control level that is out of range using a new sample from the same control vial. Pay careful attention to possible errors in technique.
         1) If the control is within acceptable limits, patient samples may be test and results reported.
         2) If the control is outside the acceptable limits, retest with a sample from a new vial.
            a) If results are in range, continue testing patient samples.
            b) If the control is still outside the acceptable limits, contact Cholestech Corp. Technical Service (800-733-0404). Do not use the Analyzer for testing patient samples until the problem is resolved.



G. Records
Daily QC logs, corrective action reports and client records must be filed for two years before destruction. Daily QC logs and corrective action reports must be reviewed by the site coordinator on a monthly basis. All laboratory documentation must be reviewed and signed by either the Technical Consultant or the Laboratory Director on a routine basis.

H. Maintenance and cleaning
1. No maintenance is required other than routine cleaning.
2. Clean the outside of the Cholestech LDX analyzer case with a clean, damp cloth. If necessary, a mild detergent or disinfectant (such as a freshly prepared 5% bleach solution) may be used. **Do not** immerse the Analyzer in water or other cleaning fluid. **Do not** use any abrasive cleaner.
3. When necessary, clean inside the cassette drawer with a cotton swab moistened with water, a 70% isopropyl alcohol solution, a 5% bleach solution, or disinfectant. Dry the cassette drawer with a second (unused) cotton swab.

VI. Step by step Procedure:

A. Start up
1. Check that the ROM pack is completely inserted and the clip is in place.
2. Insert the power supply plug into the round socket in the back of the Analyzer.
3. Plug the power supply into the wall outlet and turn the instrument on. Allow time for instrument to warm up.
IMPORTANT: Do not remove the ROM pack while the Analyzer is plugged in. The Analyzer will lose its optical calibration and will no longer function.
4. Remove the number of cassette pouches from the refrigerator that you will need and check that they have not expired. Allow the cassettes to reach room temperature for at least 10 minutes before opening.
5. Remove the cassette from its pouch. Hold the cassette by the short sides only. **Do not touch the black bar or the brown magnetic stripe.** Place the cassette on a flat surface.
6. Press **RUN**. The Analyzer will do a selftest, and the screen will display:
Selftest running
Selftest OK (upon completion of the selftest).
7. The cassette drawer will open, and the screen will display:
Load cassette and press RUN
8. Perform daily calibration procedure as described below.
9. Perform quality control if necessary.

B. Optics Check:
1. Press the **RUN** button to open the cassette drawer. This message will appear:
Load cassette and press run

2. Remove the Optics Check Cassette from the case and place it in the cassette drawer.
3. Press **RUN** to initiate the optics check test.
4. The Analyzer will automatically perform the optics check. The words "Optics Check" and four numbers will appear on the screen, one for each optical channel in the analyzer.
   Optics Check
   ch#1-ch#2-ch#3-ch#4
5. Record the results of the optics check test on the Cholestech QC log sheet.
6. Check to verify that the four numbers are within the acceptable range printed on the Optics Check Cassette.
7. Return the Optics Check Cassette to the case. The Optics Check Cassette must be stored in its case in a stable area at **room temperature.**
8. If the optics check results are out of the expected range, the following message will appear:
   Optics Test Fail
   ch#1-ch#2-ch#3-ch#4
   If this message appears, repeat the calibration. If results are still out of range, retest with a new Optics Check Cassette. Patient testing may not be performed until the optic check results are within the expected range.
9. If an expired Optics Check Cassette is used, the following message will appear:
   Expired Cassette
   ch#1-ch#2-ch#3-ch#4
10. If an expired Optics Check Cassette is used, and then a test cassette is used, the following message will appear following the test results:
    Expired Optics Cassette

C. Fingerstick Procedure

1. If possible, the patient should sit quietly for five minutes before the blood sample is collected.
2. Put a capillary plunger into the end of a Cholestech capillary tube with the red mark. Set it aside.
3. Choose a spot **on the side of one of the center fingers** of either hand. To help increase blood flow, the fingers and hands should be warm to the touch. To warm the hand you can:
   a. Wash the patient's hand with warm water, or
   b. Apply a warm (not hot) compress to the hand for several minutes, or
   c. Gently massage the finger from the base to the tip several times to bring the blood to the fingertip.
4. Clean the site with an alcohol swab. Dry thoroughly with a gauze pad before pricking the finger.
5. Firmly prick the selected site with a lancet.
6. Squeeze the finger gently to obtain a large drop of blood. Wipe away this first drop of blood, as it may contain tissue fluid.

7. Gently squeeze the finger downward until a second large drop of blood forms. Do not milk the finger. The puncture should provide a free-flowing drop of blood.
8. Hold the capillary tube horizontally by the end with the plunger. Touch it to the drop of blood without touching the skin. The tube will fill by capillary action up to the black mark. Do not collect air bubbles. If it is necessary to collect another drop of blood, wipe the finger with gauze then massage again from base to tip until a large drop of blood forms.
9. Fill the capillary within 10 seconds.
10. Wipe off any excess blood from the finger and have the patient apply pressure to the puncture until the bleeding stops.
11. Suggestions to obtaining consistent fingersticks:
    a. Perform a deep and firm puncture.
    b. Keep the patient's hand below the level of his/her heart.
    c. Hold the capillary tube at a slight descending angle to the drop of blood.
    d. Fill the capillary in less than 10 seconds.
    e. Dispense the blood from the capillary tube in less than five minutes.
    f. If blood stops flowing, wipe the finger firmly with gauze.

D. Testing Procedure

1. Perform finger stick as described above.
2. Collect sample into the capillary tube; let it draw all the way to the plunger. Do not squeeze the patient's finger tip to get more blood! You may massage the finger gently during collection. The capillary tube is pre-calibrated to measure 35 µL and contains lithium heparin anticoagulant. Do not substitute capillary pipettes from another source.
3. Within four (4) minutes, dispense all the sample from the capillary tube directly into the small well in the center of the cassette. Don't squirt the sample out of the capillary, dispense the sample smoothly and entirely. Keep the cassette after the sample has been applied.
4. Immediately place the cassette into the drawer of the Analyzer. The black reaction bar must face toward the Analyzer. The brown magnetic stripe must be on the right. **WARNING: Allowing the sample to sit in the cassette will cause inaccurate results.**
5. Press the RUN button. Do not push in the tray. The drawer will close automatically. During the test the screen will display:
   (Name of Test)
   Test Running ****
6. When the test is complete, the Analyzer will beep and the result will appear as follows;
   (Name of Test)=### (where ### is the numeric result)
   warnings
7. Press **DATA** to view the calculated results.
8. When the results are outside the measuring range of the test, the screen

will display:

[Name of Test] > ###
or:
[Name of test] < ###

9. If there is a problem with the test, a message will appear on the screen. See the Troubleshooting and Maintenance Section of the User Manual, pages 32-35, for further instructions.
10. Record the result on the daily worksheet or patient record.
11. When the drawer opens, remove the cassette and dispose of it in a biohazardous waste container. Leave the Analyzer drawer when not in use.
12. To run another test cassette, press **RUN** once.
    Load cassette and press RUN.
13. Repeat Step 3, and steps 8 through 17.
14. If the LDX is not used for another test within four minutes, a beep will sound and the screen will display:
    System timeout
    RUN to continue
    IMPORTANT: If the run button is not pushed within 15 seconds, the drawer will close and the screen will go blank.
15. If necessary, press the **DATA** button to view the results from the last cassette tested.

VII. Results

A. Cholesterol and Triglycerides

The National Heart, Lung and Blood Institute issued the Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) in May 2001. The ATP III report presented the NCEP's updated clinical guidelines for cholesterol testing and management and described the following classifications for cholesterol and triglyceride testing:

1. Adult Lipid Classification:

Test	optimal	Near Optimal/ Above Optimal	Borderline High	High	Very High
Total Cholesterol (mg/dL)	<200	-------	200-239	>240	------
HDL-Cholesterol (mg/dL)*	< 40 - low ≥ 60 - high	-------	-------	-----	-------
LDL-Cholesterol (mg/dL)	<100	100-129	130-159	160-189	≥ 190
triglycerides (fasting) (mg/dL)	<150	-------	150-199	200-499	≥ 500

* The ATP III report identified HDL cholesterol below 40 mg/dL as associated with increased risk of coronary heart disease in men and women. A high HDL-cholesterol level greater than or equal to 60 mg/dL is protective and decreases CHD risk.

2. Critical Results: Results in excess of elevated range should be noted and the client referred to their physician. The WISEWOMAN program has a critical value for Total Cholesterol of greater than 400. This value has been defined by CDC. Any client has a total cholesterol reading of greater than 400, should be referred to a health care provider and seen within 7 days of the clinic visit.

Glucose

A. The American Diabetes Association has modified the criteria for fasting plasma glucose (FPG) and the diagnosis of diabetes mellitus.

	Fasting	Impaired Fasting	Provisional diagnosis of diabetes
FPG	< 100 mg/dL	100 – 125 mg/dL	≥126 mg/dL

B. The revised criteria for diagnosis of diabetes:
   1. Symptoms of diabetes plus casual plasma glucose concentration ≥ 200 mg/dL. Casual is defined as any time of day without regard to time since last meal. (The classic symptoms of diabetes include polyuria, polydipsia, and unexplained weight loss.)
   2. FPG >126 mg/dL. Fasting is defined as no caloric intake for at least 8 hours.
   3. 2 hr. post glucose load ³200 mg/dL during an oral glucose tolerance test. The test should be performed as described by WHO (World Health Organization) using a glucose load containing the equivalent of 75-g anhydrous glucose dissolved in water.
   4. Any of the above abnormal glucose levels must be confirmed, on a subsequent day, by any one of the three methods listed above. When screening for diabetes, any abnormal glucose result should be referred to a physician for further follow-up.
   5. The WISEWOMAN program has established an alert value for Glucose of greater than 375. This value has been defined by CDC. A client with a glucose reading, (fasting or casual) of greater than 375 should be referred to a health care a provider and seen within 7 days of the clinic visit.

VIII. Limitations of method

A. The glucose test is specific for D-glucose. Other sugars that may be present in the blood do not react in the glucose test (i.e., fructose, lactose).
B. Samples with total cholesterol, HDL cholesterol, triglyceride or glucose values outside the measuring range should be sent for retesting and evaluation.
C. Performance of the Cholestech LDX System has not been tested on samples from newborns.

D. Some substances may cause false results with enzymatic tests. The substances listed in the manufacturers package insert below were tested for all analytes. Less than 10% interference was seen at the levels stated by the manufacturer.

IX. Procedural Notes.

A. The LDX should be left plugged in to maintain power to internal battery chip except when packed to move. It may remain unplugged for several days if needed for extended travel, but must be stored with power applied.

B. Further information may be obtained at the Cholestech website: www.cholestech.com/products/ldx_documentation. Documents which may be downloaded from this website include the LDX System User Manual, Procedure Manual, Quick Reference Guide, and Routine Operating Procedures. Laboratory staff is encouraged to download these documents and thoroughly read through them

VIII. References

A. Cholestech L-D-X Lipid Analyzer User Manual. Cholestech Corp., 3347 Investment Blvd., Hayward, CA 94545 (800) 773-0404.

B. Cholestech LDX Lipid Panel-Glucose Package Insert.

C. Expert Panel on Detection, Evaluation, and Treatment of High Cholesterol in Adults. Executive summary of the Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Cholesterol in Adults (Adult Treatment Panel III). Journal of the American Medical Association, 2001; 285:2486-97.

D. Report of the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus. Diabetes Care 2004; vol. 27, Supplement 1:SS-10.

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This material reviewed and approved for use without modification:

Review Date/Signature: _____

Review Date/Signature: _____

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Review Date/Signature: _____

Review Date/Signature: _____

Review Date/Signature: _____

RL.18.02
Rev. 5/2007

Health Management Systems, Corp.
6913 K Ave.
Suite 304
Plano, TX 75074
Phone (972) 578-2390 **Fax** (972) 578-9854

Quote

Quote No: 10247

Quote To: **State of Missouri - Dept. of Mental Health**
Attn: Kellie Shuck
1706 Elm Street
Jefferson City, MO 65101

Ship To: **State of Missouri - Dept. of Mental Health**
Attn: Kellie Shuck
1706 Elm Street
Jefferson City, MO 65101

Customer No: Access ID No:

Date	Ship Via	Terms	F.O.B.
2/7/2011		Net 30 Days	Origin

Quote Expiration Date	Sales Person	Date Product Required
5/8/2011	Brian Bullock	

Quantity Required	Quantity Shipped	Quantity B.O.	Item Number	Description	Unit Price	Amount
1			13454	Cholestech Analyzer	$1,400.00	1,400.00
				Includes: Analyzer, Power Supply, Optics Check Cassette, &		-
				Users Manual		-
21			10991	Lipid Profile + Glucose Cassettes (10/box)	$101.49	2,131.29
4			10940	Capillary Tubes 35 uL (50/vial)	$12.86	51.44
4			10311	Capillary Plungers (50/vial)	$5.42	21.68
1			10983	Level 1 & 2 Controls - Lipid (3 sets)	$94.05	94.05
1			11846	Mini-Pet Pipette 35uL (each)	$14.44	14.44
1			11010	Pipette Tips (50/bag)	$5.23	5.23
2			24082341	VitalCare Lancets - Pink-Needle (100ct)	$18.00	36.00
						-
1			Staff Training	Inverness Medical/Cholestech Rep. will perform (One)	$0.00	-
				Staff Training at your location at No Charge		-
						-
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Notes: Freight cost is based on weight of product and will be determined at time of shipment.

Sub Total	$ 3,754.13
Freight	$ -
Sales Tax	$ -
Grand Total	**$ 3,754.13**

Thank You

Health Management Systems, Corp.
6913 K Ave.
Suite 304
Plano, TX 75074
Phone (972) 578-2390 **Fax** (972) 578-9854

Quote

Quote No: 10248

Quote To: **State of Missouri - Dept. of Mental Health**
Attn: Kellie Shuck
1706 Elm Street
Jefferson City, MO 65101

Ship To: **State of Missouri - Dept. of Mental Health**
Attn: Kellie Shuck
1706 Elm Street
Jefferson City, MO 65101

Customer No: Access ID No:

Date	Ship Via	Terms	F.O.B.
2/7/2011		Net 30 Days	Origin

Quote Expiration Date	Sales Person	Date Product Required
5/8/2011	Brian Bullock	

Quantity Required	Quantity Shipped	Quantity B.O.	Item Number	Description	Unit Price	Amount
1			13454	Cholestech LDX Analyzer	$1,400.00	1,400.00
				Includes: Analyzer, Power Supply, Optics Check Cassette, &		-
				Users Manual		-
1			14973	Cholestech LDX Printer	$400.00	$400.00
				Includes: Printer Power Supply, & Starter Roll (200) Labels		-
						-
						-
						-
						-
						-
						-
1			Staff Training	Inverness Medical/Cholestech Rep. will perform (One)	$0.00	-
				Staff Training at your location at No Charge		-
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						-
						-

Notes: Freight cost is based on weight of product and will be determined at time of shipment.

Sub Total	$ 1,800.00
Freight	$ -
Sales Tax	$ -
Grand Total	**$ 1,800.00**

Thank You

Health Management Systems, Corp.
6913 K Ave.
Suite 304
Plano, TX 75074
Phone (972) 578-2390 **Fax** (972) 578-9854

Quote

Quote No: 10249

Quote To: **State of Missouri - Dept. of Mental Health**
Attn: Kellie Shuck
1706 Elm Street
Jefferson City, MO 65101

Ship To: **State of Missouri - Dept. of Mental Health**
Attn: Kellie Shuck
1706 Elm Street
Jefferson City, MO 65101

Customer No: Access ID No:

Date	Ship Via	Terms	F.O.B.
2/7/2011		Net 30 Days	Origin

Quote Expiration Date	Sales Person	Date Product Required
5/8/2011	Brian Bullock	

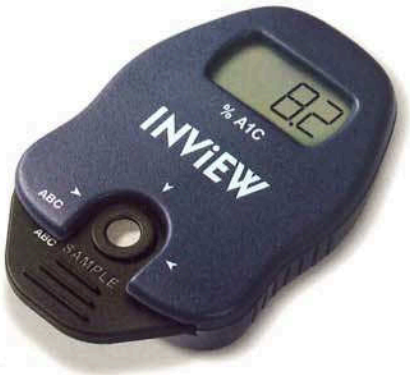
Quantity			Item Number	Description	Unit Price	Amount
Required	Shipped	B.O.				
1			14973	Cholestech Printer	$400.00	400.00
				Includes: Printer Power Supply & Starter Roll (200) Labels		-

Notes: Freight cost is based on weight of product and will be determined at time of shipment.

Sub Total	$ 400.00
Freight	$ -
Sales Tax	$ -
Grand Total	**$ 400.00**

Thank You

QUICK START GUIDE



A1cNow® INVIEW™

MULTI-TEST A1C SYSTEM

PLEASE READ BEFORE USING PRODUCT

This Test is Important to Your Patients.

Immediate A1C Exam-Room Testing May Help Reduce Patient A1C Results. The impact of face-to-face A1C discussions may reduce A1C values up to 1%.[1,2] It's been shown that a 1% reduction in A1C lowers risk of complications such as eye, kidney and nerve disease by 40%[3]

BEFORE YOU TEST

Review the A1cNow® InView™ Procedure Card located inside the top of the product box.

Remember!

1. Use product at room temperature.
2. Prepare blood sample before you open Test Cartridge Pouch. (Pouch #2).
3. Confirm that monitor and test cartridge codes match before you perform the test.

4. Diluted Sample must be added within 2 minutes of opening pouch.
5. Do not add sample until the cartridge has been inserted and "SMPL" appears on the monitor display.

6. Result will display for ONLY 30 minutes or until next cartridge is inserted.

(Continue on to next page)

A1cNow InVIEW
MULTI-TEST A1C SYSTEM

PROFESSIONAL-USE PRODUCT INSERT

METRIKA

This test is WAIVED under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). If a laboratory modifies the test instructions, the test will no longer be considered waived.

Intended Use

The A1cNow® InView™ test provides quantitative measurement of the percent of glycated hemoglobin (%A1C) levels in capillary (fingerstick) or venous whole blood samples. The test is for professional use to monitor glycemic control in people with diabetes.

Summary and Explanation

High levels of blood glucose result in over-glycation of proteins throughout the body, including hemoglobin[1]. Glycation of hemoglobin can occur at the amino termini of the alpha and beta chains, as well as other sites with free amino groups[1]. Hemoglobin A undergoes a slow glycation with glucose that is dependent on the time-average concentration of glucose over the 120-day life span of red blood cells.

The most prevalent and well-characterized species of glycated hemoglobin A is A1C, making up approximately 3% to 6% of total hemoglobin in healthy individuals[1]. The correlation of A1C and blood glucose levels make it a useful method of monitoring long-term blood glucose levels in people with diabetes[2]. Previous studies, such as the Diabetes Complications and Control Trial (DCCT) and the United Kingdom Prospective Diabetes Study (UKPDS), used glycated hemoglobin as a way to measure overall glycemic control during the studies. These studies, and others, have shown that tight glycemic control is associated with fewer diabetes-related complications (e.g., vision problems, cardiovascular problems, and kidney problems)[3]. The National Glycohemoglobin Standardization Program (NGSP) was established to assure traceability of hemoglobin A1C (A1C) results to the DCCT. Studies show a direct relationship from %A1C to average blood glucose (MBG) levels. For every 1% change in A1C there is a change of about 30 mg/dl in MBG[4]. The formula used to calculate the mean (average) blood glucose levels from the A1C levels is MBG = (31.7 x HbA1c) - 66.1. To convert to mean plasma glucose (MPG) use[5] MPG = MBG x 1.11.

A1C can be measured by a variety of techniques, and over the past decade they have expanded to include point-of-care assays. Point-of-care assays are well suited to environments such as physicians' offices and clinics, because they are generally easy to perform, require no laboratory equipment, and provide rapid turn-around-time from sampling to result[6]. This immediate feedback of results enhances physician/patient interaction and, therefore better enables disease management[7].

Principle of the Assay

Metrika has developed an enabling technology called MODM™ (Micro-Optical Detection Method) that incorporates microelectronics, optics, and dry-reagent chemistry strips within a reusable, self-contained, integrated hand held monitor and a single-use test cartridge. An unmeasured whole blood mixture (diluted) is directly applied to the sample port, and results are displayed in numeric form on the monitor's liquid crystal display after 5 minutes. Having no switches or buttons, the monitor self-activates upon insertion of the Test Cartridge.

The A1cNow InView monitor utilizes both immunoassay and chemistry technology to measure A1C and total hemoglobin, respectively. Upon the addition of a diluted blood sample, blue microparticles conjugated to anti-A1C antibodies migrate along the reagent strips. The amount of blue microparticles captured on the strips reflects the amount of A1C in the sample.

For the total hemoglobin (Hb) portion of the test, the sample diluent converts Hb to met-Hb. The intensity of met-Hb color measured on the reagent strips is proportional to the concentration of hemoglobin in the sample. Test results are expressed as %A1C (A1C ÷ total Hb x 100).

Calibration of the A1cNow InView is performed with a set of blood samples that have been value-assigned by a National Glycohemoglobin Standardization Program (NGSP) certified laboratory using an NGSP reference method. Total Hb calibration values for those samples are obtained with a Total Hb analyzer (HemoCue B-Hemoglobin System, HemoCue Ab, Ångelholm, Sweden). The calibration of the A1cNow InView test is thus traceable to the NGSP and to an NGSP Certified Network reference method.

Specimen Collection and Storage

Note: No fasting or special diet is necessary

Fingerstick

The A1cNow InView test requires 10 microliters (µL) of whole blood (1 large drop). Fingerstick blood is obtained by standard techniques with any lancing system. If alcohol is used for cleansing, be sure the finger is completely dry before lancing.

Venipuncture

Venous blood is to be collected in an EDTA tube ("Purple Top"). Blood should be well-mixed, and tested at room temperature. Venous blood samples are stable for up to 8 hours at room temperature, and up to 14 days if refrigerated (2-8°C).

Warnings and Precautions

1. For in vitro diagnostic use only.
2. Carefully read and follow the "Procedure" section to ensure proper test performance.
3. If refrigerated, bring sealed pouches to room temperature for one hour.
4. The A1cNow InView Monitor and Test Cartridges should not be used if either are cracked or broken.
5. The Test Cartridges should not be used if the foil pouch is damaged.
6. Add sample to A1cNow InView Test Cartridge within 2 minutes after pouch is opened.
7. Handle and dispose of all samples and pipets following appropriate biohazard procedures.
8. The Dilution Buffer contains ferricyanide in a buffered detergent solution. Do Not Ingest. In case of contact with skin or eyes, flush the area with large amounts of water.
9. Do not reuse Test Cartridges or Sample Dilution Kits.

• Do not mix Monitors with Cartridges & Sample Dilution Kits from different lots.

Kit Storage and Stability

• Pouched Test Cartridges, A1cNow InView monitors, and Sample Dilution Kits may be stored at room temperature (18-28°C) for up to **three months** prior to use. Monitors, Test Cartridges, and Dilution Kits must be thrown away if not used within the **three months**.

• The Monitors, Test Cartridges, and Sample Dilution Kits may be used until the expiration date printed on the box and pouches when stored refrigerated (2-8°C). Monitors, Test Cartridges, and Sample Dilution Kits must be thrown away if not used by the expiration date.

• Leave all components in their sealed pouches until use. If refrigerated, ensure pouches are at room temperature before use.

• Do not mix pouches and Monitors from different lots.

Package Components

• A1cNow InView Monitor (1)

• A1cNow InView Test Cartridges (10, or 20)
Each Test Cartridge includes the following chemistries: antibody to HbA1c, antigen conjugate that binds to the antibody, and membranes.

• Sample Dilution Kit (10, or 20), each containing:

Tube (1), containing 0.69 mL of buffered detergent solution with ferricyanide

Capillary (1)

Dropper (1)

Tube Holder (1)

• Product insert (1)

• Procedure card (1)

• Patient result labels (10, or 20)

Materials Required but Not Supplied

• Fingerstick sample: lancet, or other blood fingerstick collection device or,

• Venous sample: EDTA tube ("purple top"), venous collection supplies, as well as:

• Gauze pad or cotton ball

• Bandage

PROCEDURE

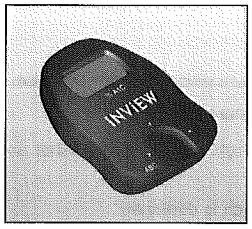
Make sure all parts are the same lot number. Always run the test with all parts of the test kit at room temperature (18°–28°C, 64°– 82° F). If the kit has been recently at high temperatures (above 82°F) or in the refrigerator allow ALL parts to come to room temperature in their sealed foil pouches for at least one hour before running the test.

Avoid running the test in direct sunlight, on hot or cold surfaces, or near sources of heat or cold.

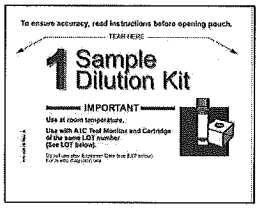
Once the A1cNow InView Monitor, Test Cartridge and Sample Dilution Kit have been at room temperature for at least one hour, open the Sample Dilution Kit and place the parts on a clean, flat surface. Test immediately.

PREPARE

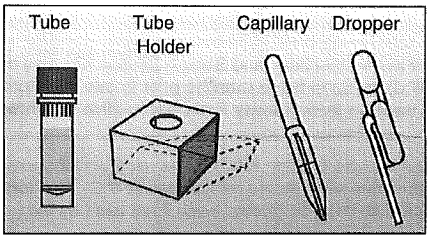
the following items. Have them all at room temperature:

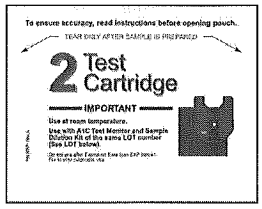


1. The Monitor



2. Sample Dilution Kit
(Open Pouch)

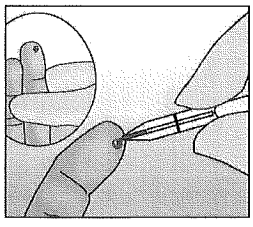




3. Test Cartridge
(Wait to open)

GET BLOOD

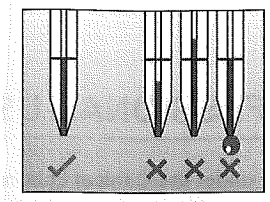
OPEN POUCH #1, then squeeze the folded Tube Holder to open it. Remove cap. Place Tube in Holder.



CLEAN AND DRY the patient's finger. Lance the finger to obtain a large (10 µL) drop of blood. Do not milk the finger.

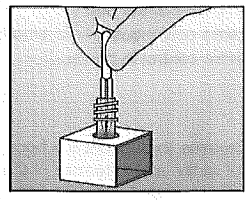
DO NOT SQUEEZE THE BULB of the Capillary during this process. Place the Capillary at a slight angle against the blood drop or blood volume and let capillary action fill the Capillary just to the black line. Pull the Capillary away and DO NOT SQUEEZE THE BULB.

NOTE: For Venous Draw Procedure: obtain a blood sample by standard venipuncture technique in an EDTA (purple top) tube. Mix the sample well before testing. A standard laboratory precision pipet may be used to transfer 10 µL from an EDTA tube into the Dilution Buffer tube, instead of the capillary pipet.



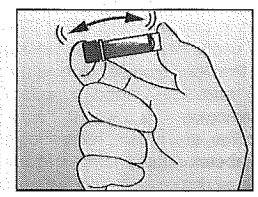
Do not underfill, overfill, or leave a hanging drop!

ADD BLOOD TO TUBE



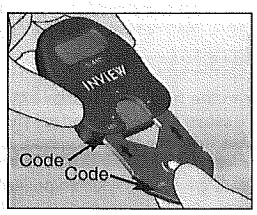
PUT CAPILLARY TIP into the liquid in the Tube. Leaving it submerged, squeeze the bulb firmly two or three times to rinse all of the blood from the Capillary into the Tube.

RECAP TUBE, SHAKE!



RECAP THE TUBE tightly and shake it vigorously 6-8 times. It's OK to have some bubbles. The diluted sample will be red-orange in color. Replace the Tube in the Tube Holder.

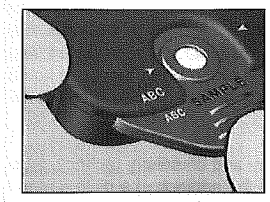
INSERT CARTRIDGE



OPEN POUCH #2 and insert Cartridge into Monitor immediately The display will turn on and show "SMPL".

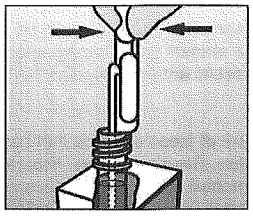
Place on a flat surface. The Monitor is now ready for use. (If you see any other message on the display, go to "Troubleshooting").

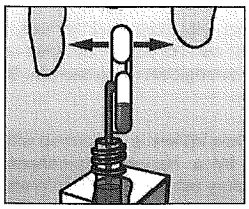
IMPORTANT: ADD DILUTED SAMPLE WITHIN 2 MINUTES!



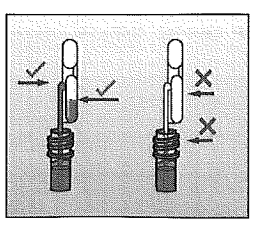
NOTE: The code on the Monitor must match the code on the Cartridge. If the code numbers do not match, DO NOT continue with the test.

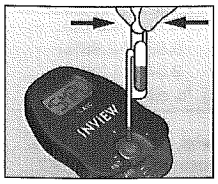
FILL DROPPER





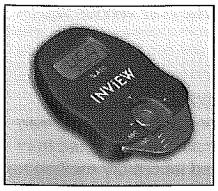
REMOVE THE CAP from the Tube. Squeeze the top bulb of the Dropper and submerge it in the liquid. Release the bulb to fill the Dropper as shown. The Dropper must be completely filled including some overflow. If not, empty and refill as described above. Two or three bubbles are OK; if there are lots of bubbles, empty and refill as described above.





ADD DILUTED SAMPLE

DO NOT TOUCH the Cartridge with the Dropper (hold the Dropper slightly above the sample well of the Cartridge). Squeeze the bulb firmly to add all of the sample ALL AT ONCE. Liquid will stay in the overflow bubble.

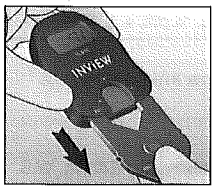


The display will start counting down from 5 minutes, then show a test result alternating with the letters "QC OK". Do not handle the Monitor until the result is displayed. The results remain displayed for 30 minutes or until the next Test Cartridge is inserted.

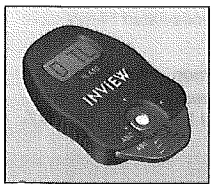
RECORD RESULT

RECORD THE RESULT immediately on the patient label provided. Results are expressed as % (percent) A1C.

REMOVE CARTRIDGE KEEP MONITOR



THE MONITOR IS REUSABLE until all the Cartridges are used up. To run a new test, start with a new Sample Dilution Kit and Test Cartridge and go to "Prepare".



The monitor will display 3 TL, 2 TL, 1 TL and 0 TL, alternating with "QC OK" and the result when there are 3, 2, 1 and 0 tests left, respectively. After all Cartridges in the kit are used, the Monitor will expire. (If you insert a new Cartridge, the display will show "0 TL" (Zero Tests Left) for five minutes and then shut down permanently.)

NOTE: If any contamination is visible inside the Monitor, call Metrika at 1-877-212-4968.

Result Interpretation

Percent A1C monitors glucose control over the last three months. About 50% of the A1C result is from the past 30 days; about 25% is from the past 30-60 days and about 25% is from the past 60-120 days[1]. Depending on the test methodology used, laboratory methods show that the reference range of the A1C test is approximately 4.0-6.5% A1C, and 6% to 9% in people with well to moderately controlled diabetes[1]. Levels can be as high as 20% in people with poorly controlled diabetes[8]. Reference range studies conducted by Metrika using the A1cNow system showed the normal range to be 3.9-6.5% A1C in the non-diabetic population tested. Reference ranges should be detemined by each laboratory to conform to the population being tested.

Troubleshooting

See the table below for a description of A1cNow InView operating and error codes (OR = Out of Range; QC = Quality Control, E= Monitor Error)

MESSAGE	DESCRIPTION AND RESOLUTION
OR 1	The Blood sample may have too little hemoglobin (less than 20% hematocrit), or there was under-sampling of whole blood.* You may wish to check hemocrit by another method.
OR 2	The blood sample may have too much hemoglobin (greater than 60% hemocrit), or there was over-sampling of whole blood.* You may wish to check hemocrit by another method.
OR 3	The blood sample may have too little A1C, or there was under-sampling of whole blood.*
OR 4	The blood sample may have too much A1C, or there was over-sampling of whole blood.*
OR 5	The monitor temperature is below 18°C (64°F). Repeat the test at room temperature (18-28°C).
OR 6	The monitor temperature is above 28°C (82°F). Repeat the test at room temperature (18-28°C).
<4.0	The %A1C is less than 4%.
>13.0	The %A1C is greater than 13%.
QC 1 to QC99	The quality control checks did not pass. Call Metrika Technical Support toll free at 877-212-4968. The test will have to be repeated with another Test Cartridge and SampleDillution Kit.
E1 to E99	The Monitor has a Fatal Error. Call Metrika Technical Support toll-free at 877-212-4968

*Carefully repeat the test using a new Test Cartridge and a new Sample Dilution Kit.

Limitations

- This test is NOT for the screening or diagnosis of diabetes.
- If the patient has high levels of Hemoglobin F, Hemoglobin S, Hemoglobin C, or other hemoglobin variants, the A1cNow system may report incorrect results.
- Any cause of shortened red cell survival (e.g., hemolytic anemia or other hemolytic diseases, pregnancy, recent significant blood loss, etc.) will reduce exposure of red cells to glucose. This results in a decrease in %A1C values. Percent A1C results are not reliable in patients with chronic blood loss and consequent variable erythrocyte life span.
- This test is designed to be run at 18-28°C (64-82°F) and 15-80% humidity. Using the monitor outside this temperature range will give an error code.
- This test is not a substitute for regular doctor visits and blood glucose monitoring.
- As with any laboratory procedure, a large discrepancy between clinical impression and test results usually warrants investigation.

Controls

Each A1cNow InView monitor performs over 25 internal chemical and electronic quality control checks, including potential hardware and software errors (e.g., autostart leads, programming), and potential reagent strip errors (e.g., insufficient sample volume, invalid calculations). The monitor has been programmed to report an error code if these quality checks are not passed.

If external quality control testing is desired, commercial controls may be purchased from other vendors. Please contact Metrika Customer Service for recommendations. Metrika recommends that external controls be tested at the following times:

1. Whenever laboratory or room conditions have been above 28°C if stored at room temperature.
2. To perform training or retraining of testing personnel.
3. Whenever A1cNow InView results do not match other clinical findings or symptoms.

Good laboratory practices include a complete quality control program. This entails proper sample collection and handling practices, ongoing training of testing personnel, ongoing evaluation of control results, proper storage of test kits, etc. A permanent record of control results should be retained.

Performance

Expected values

The expected normal range for %A1C using the A1cNow system was determined by testing blood samples from 118 presumptively non-diabetic individuals (fasting glucose levels <127 mg/dL) across three US sites. The population included 33 males and 85 females, and an age range from 19 to 76 with a mean age of 43. The mean %A1C result was 5.2% ± 0.71% (1 SD). The 95% confidence limits were 3.9% to 6.5%. These values are similar to those reported in the literature. Each laboratory should determine its own reference range to conform to the population being tested.

The expected %A1C value for patients with diabetes will depend on physician discretion. The American Diabetes Association's (ADA's) most recent Clinical Practice Recommendation for diabetes specifies a treatment goal of less than 7%, and suggests additional action when the A1C level is above 8%[9].

Linearity

Studies were performed to evaluate the linearity of the A1cNow system across its dynamic range. Clinical samples representing low and high %A1C levels were identified, and were mixed in various proportions into nine preparations. These samples were tested in replicates of at least five (n = 5). The observed results were compared to the expected results and analyzed in terms of percent recovery. The test is linear for %A1C levels between 4% and 13%, and produces reliable results with hematocrits between 20% and 60% packed cell volume (PCV).

Interference Testing/Specificity

Studies were performed to assess the effect of common test interferents, various common over-the-counter therapeutic agents, and oral antihyperglycemic agents commonly used to treat Type II diabetes. Two levels of %A1C (low and high, approximately 4% and 10%, respectively) were tested. See table below.

INTERFERENT	TEST CONCENTRATION
Bilirubin (unconjugated)	20 mg/dL
Triglyceride	3000 mg/dL
Hemoglobin	500 mg/dL
Acetamnophen	80 mg/dL
Ascorbic acid	5 mg/dL
Ibuprofen	120 mg/dL
Acetylsalicyclic acid	1 mg/dL
Glyburide (glibenclamide)	240 mg/dL
Metformin (1.1-dimenthylbiguanide HCl)	25 mg/dL

The studies showed no effect from any of these potential interferents at concentrations up to approximately 5-times their normal levels or therapeutic doses.

Studies showed no interference from modified hemoglobins, including labile glycated hemoglobin when tested at two levels of %A1C (low and high, approximately 5% and 11% respectively). The modified hemoglobins, and the levels evaluated, were: labile hemoglobin with 1400 mg/dL glucose, carbamylated hemoglobin at a final concentration of 5 mM potassium cyanate, and acetylated hemoglobin at a final concentration of 14 mM acetylsalicylic acid.

There were mixed results from the testing of high levels of Hemoglobin F, Hemoglobin S, and Hemoglobin C. Unreliable results may be obtained from patients with elevated levels of variant hemoglobins.

Precision
Precision testing was done under a specialized protocol. Following this protocol, two whole blood samples, one of approximately 6 %A1C (low), and one of approximately 9 %A1C (high), were tested over 20 days and four runs per day, for a total of 80 assays per level. The overall imprecision (including within-day and between-day) was 2.97% CV at the low level and 4.14% CV at the high level. This performance meets the requirements of NGSP certification.

Accuracy
Accuracy studies were conducted with 189 diabetic and non-diabetic subjects across three US sites. Fingerstick sampling was performed on each subject for testing with A1cNow InView, and venous blood was collected from each subject for comparative testing using an NGSP-certified method. A1cNow InView results were compared to the NGSP reference results. The A1C results ranged from 5.0 %A1C to 12.8 %A1C, with a mean of 7.3 %A1C (reference results). Data analysis consisted of least squares linear regression (x = reference results), bias calculation, and Bland Altman limits. The data are provided below.

A1cNow InView Fingerstick Comparative Testing
(NGSP-certified method is the Tosoh A1c 2.2 Plus)

n	189	Bias at 6% A1C (% difference)	5.89 (- 1.83%)
slope	1.02	Bias at 7% A1C (% difference)	6.91 (-1.29%)
y-intercept	- 0.23	Bias at 9% A1C (% difference)	8.95 (- 0.56%)
"r"	0.95		Avg. % diff. - 1.23%

The results showed that the accuracy of A1cNow InView, with fingerstick samples, was, on average, 99%. This means that, on average, a true 7 %A1C could read approximately 6.9 %A1C. An individual A1cNow InView result may differ by as much as -1.0 %A1C to +0.8 %A1C from the true result. This represents the 95% confidence limits of a Bland-Altman plot.

A1cNow System Venous Comparative Testing
(NGSP-certified method is the Tosoh A1c 2.2 Plus)
In a separate study, venous blood was collected from 50 diabetic subjects, and each sample was tested twice by three different lots (total of six results, two replicate tests from one dilution). Aliquots of the venous samples were also tested by the NGSP-certified method, providing approximately 300 comparative results. Data analysis again consisted of least squares linear regression (x = reference results), bias calculation, and Bland Altman limits. The data are provided below.

n	299	Bias at 6% A1C (% difference)	5.77 (- 3.83%)
slope	1.023	Bias at 7% A1C (% difference)	6.801 (-2.86%)
y-intercept	-0.361	Bias at 9% A1C (% difference)	8.84 (- 1.78%)
"r"	0.90		Avg. % diff. - 2.82%

The results showed that the accuracy with venous sampling was, on average, 97%. This means that, on average, a true 7 %A1C could read approximately 6.8 %A1C. An individual result may differ by -1.3 %A1C and +0.9% A1C from the true result. The A1cNow system may be used with either fingerstick (capillary) or venous (EDTA anticoagulated) whole blood samples.

Expected Performance in Waived Laboratories
Clinical studies were performed at three US sites with over 180 untrained people (most with diabetes). These study subjects read the instructions and then performed one A1cNow InView test on themselves. A venous blood sample was collected from each subject, and this sample was tested by an NGSP-certified laboratory method for %A1C. The two results were then compared.

Untrained User A1cNow InView and an NGSP-certified method
(Tosoh A1c 2.2 Plus)

n	188	Bias at 6% A1C (% difference)	6.02 (+ 0.33%)
slope	0.99	Bias at 7% A1C (% difference)	7.01 (+0.14%)
y-intercept	0.08	Bias at 9% A1C (% difference)	8.99 (- 0.11%)
"r"	0.93		Avg. % diff. + 0.12%

The results showed that untrained users could perform A1cNow InView testing on themselves with the same accuracy as trained individuals.

References

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2. Nathan, D.M., et al. The clinical information value of the glycosylated hemoglobin assay. N Engl J Med 1984; 310; 341-346.

3. The Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complication in insulin-dependent diabetes melllitus. N Engl J Med 1993; 329; 977-986.

4. Diabetes Care 1999; 22 (Suppl. 1); S32-S41.

5. Fogh-Anderson, N., D'Orazio, P.; Proposal for standardizing direct-reading biosensors for blood glucose. Clin Chem 1998; 44(3); 655-659.

6. MLO Supplement, Point-of-Care Testing, 1992.

7. Cagliero, E., Levina, E.V., Nathan, D.M.; immediate feedback of A1C levels improves glycemic control in type 1 and insulin-treated type 2 diabetic patients. Diabetes Care 1999; 22(11): 1785-1789.

8. Goldstein, D.E., Little, R.R., Wiedmeyer, H.M., et al.; Glycated hemoglobin: Methodologies and clinical applications. Clin Chem 1986; 32: B64-B70.

9. American Diabetes Association. Standards of Medical Care for Patients with Diabetes Mellitus (Position Statement). Diabetes Care 2000; 23 (Suppl. 1): S32-S42.

METRIKA

510 Oakmead Parkway, Sunnyvale, CA 94085-4022
Toll Free: 877-212-4968 · Phone: (408) 524-2255
FAX: (408) 524-2252 · www.metrika.com

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TRAINING

Take the easy to follow training exam on the A1cNow InView System to receive your certificate of completion.

INFORMATIVE FACT SHEETS

The following fact sheets are available by calling 877-212-4968 ext. 522.

- **NGSP-Certified Performance Summary** – Documentation demonstrating the A1cNow InView System is certified by the NGSP.
- **Billing for A1cNow InView** – Simple guide to billing & reimbursement.
- **Sources of Variation** – Helps answer questions and interpret differences you may see between results when using A1cNow InView and other A1C methods performed in laboratories.
- **Patient Chart** – Allows you to easily chart the progress of your patients.
- **Quality Control Log** – Allows you to track operator ID, patient ID, patient results, internal Qc message and comments/actions.
- **A1cNow InView Is Certified by the NGSP** - Support documentation for NGSP certification.
- **Certification & Training Exam** - Allows for quick and easy training along with self-certification.
- **Certificate of Completion** – Certificate provided once you pass the certification & training exam.

A1cNow INVIEW
MULTI-TEST A1C SYSTEM

1 Miller CD et al., Rapid A1c availability improves clinical decision-making in an urban primary care clinic. Diabetes Care 2003; 26:1158-1163.

2 Cagliero E et al., Immediate feedback of HbA1c levels improves glycemic control in type 1 and insulin-treated type 2 diabetic patients. Diabetes Care 1999; 22: 1785-1789.

3 Centers for Disease Control and Prevention. National diabetes fact sheet: general information and national estimates on diabetes in the United States, 2002. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2003.

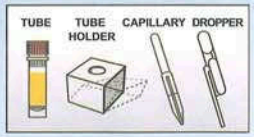
P/N 90638 Rev. A

PREPARE

Prepare the following items. Have them all at room temperature:

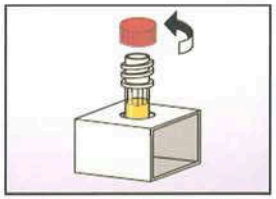
1. THE MONITOR

2. SAMPLE DILUTION KIT (OPEN POUCH)

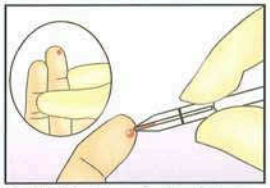


3. TEST CARTRIDGE (WAIT TO OPEN)

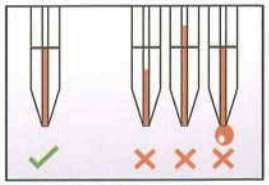
GET BLOOD



1. Set up Holder. Remove cap. Place Tube in Holder.

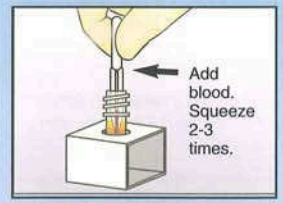


2. Fill Capillary to the black line. Do not squeeze.

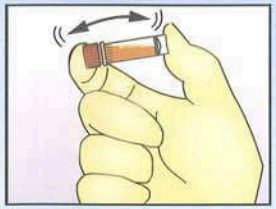


Do not underfill, overfill, or leave a hanging drop.

ADD BLOOD. SHAKE!



1. Squeeze blood into Tube. Rinse Capillary thoroughly with solution.

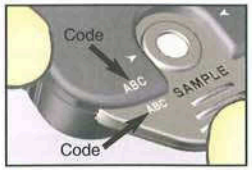


2. Recap Tube. Shake vigorously 6 – 8 times.

INSERT CARTRIDGE

1. Open Pouch #2 and insert Cartridge into Monitor immediately.

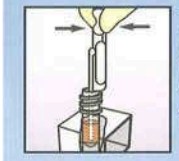
Diluted sample must be added within 2 minutes.



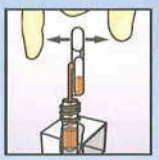
Monitor and Cartridge code must match.

2. "● SMPL" will appear on display. It is now ready for use.

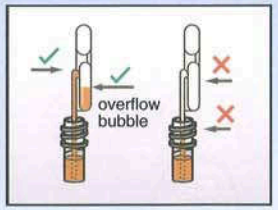
FILL DROPPER



1. Squeeze Dropper, insert in diluted sample.

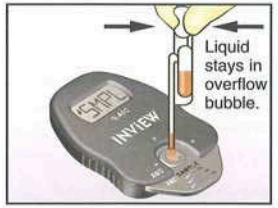


2. Release slowly. Leave Dropper in Tube.

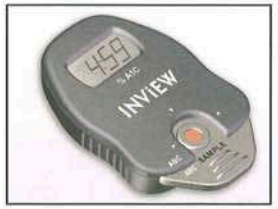


Liquid in overflow bubble ensures good fill.

ADD DILUTED SAMPLE



1. Place Monitor on a flat surface. Squeeze Dropper firmly to add sample all at once.



2. The Monitor will start counting down from 5 minutes.

READ RESULT

1. The result will alternate with "QC OK" on the screen. Otherwise, see error codes (back of insert).

2. When the test is finished, remove the Cartridge and throw it away.

The Monitor is reusable. Save for the next test.

OPERATING MESSAGES

Display	Message	What to Do
	NOTE DETAIL	Monitor initializing. Wait for SMPL.
	SMPL	Monitor ready for sample application. Proceed with test.
	QCOK	Quality controls OK. Read result.
	6.7	Result will display on the Monitor up to 30 minutes or until a new Cartridge is inserted.
	3TL - 0TL	3 to 0 tests left. At 0 tests left, it's time to reorder.

If you get a message on the display of your Monitor with letters and/or symbols, follow "What to Do" in the tables shown. If you get an error code, you will NOT get a test result number. The test will have to be repeated with another test cartridge to get the A1C result. Call 1-877-212-4968 for technical support.

METRIKA

Metrika, Inc.
510 Oakmead Parkway
Sunnyvale, CA 94085-4022

ERROR CODES

Display	Message	What to Do
	OR1	The blood sample may have too little hemoglobin (less than 20% hematocrit), or there was under-sampling of whole blood.* You may wish to check hematocrit by another method.
	OR2	The blood sample may have too much hemoglobin (greater than 60% hematocrit), or there was over-sampling of whole blood.* You may wish to check hematocrit by another method.
	OR3	The blood sample may have too little A1C, or there was under-sampling of whole blood.*
	OR4	The blood sample may have too much A1C, or there was over-sampling of whole blood.*
	OR5	The monitor temperature is below 18˚C (64˚F). Repeat the test at room temperature (18-28˚C).*
	OR6	The monitor temperature is above 28˚C (28˚F). Repeat the test at room temperature (18-28˚C).*
	<4.0	The %A1C is less than 4%.
	>13.0	The %A1C is greater than 13%.
	QC1 - QC99	The quality control checks did not pass. Call Metrika Technical Support toll free at 877-212-4968. The test will have to be repeated with another Test Cartridge and Sample Dilution Kit.
	E1 - E99	The Monitor has a General Device Error. Call Metrika Technical Support toll free at 877-212-4968.
		*Carefully repeat the test using a new Test Cartridge and a new Sample Dilution Kit.

NOTES

Please record any errors below.

P/N 90610 Rev. A

METRIKA

A1C TEST

A1cNow INVIEW

MULTI-TEST A1C MONITOR

Health Management Systems, Corp.
6913 K Ave.
Suite 304
Plano, TX 75074
Phone (972) 578-2390 **Fax** (972) 578-9854

Quote

Quote No: 10253

Quote To: **State of Missouri - Dept. of Mental Health**
Attn: Kellie Shuck
1706 Elm Street
Jefferson City, MO 65101

Ship To: **State of Missouri - Dept. of Mental Health**
Attn: Kellie Shuck
1706 Elm Street
Jefferson City, MO 65101

Customer No: Access ID No:

Date	Ship Via	Terms	F.O.B.
2/10/2011		Net 30 Days	Origin

Quote Expiration Date	Sales Person	Date Product Required
5/11/2011	Brian Bullock	

Quantity			Item Number	Description	Unit Price	Amount
Required	Shipped	B.O.				
1			3021	Bayer A1c NOW Plus (Box of 20)	$192.00	192.00

Notes: Please note that this product is temperature sensitive and requires Overnight Shipping. Freight cost is based on weight of product and will be determined at time of shipment.

Sub Total	$ 192.00
Freight	$ -
Sales Tax	$ -
Grand Total	**$ 192.00**

Thank You

Hgb A1c Monitors

[Diabetic Care Choice DMÂ™ A1C Home Test Kit - 1 Single-Use A1C]

Results in only **8 minutes**< For the quantitative measurement of the percent of glycated hemoglobin (%HbA1c) levels using a fingerstick blood sample.

Item Code: COC824243

Price: $22.99

Brand: Bristol-Myers Squibb

http://www.shopwiki.com/_Diabetic+Care+Choice+DM%C2%99+A1C+Home+Test+Kit+-+1+Single-Use+A1C?o=299494767&s=240890

Bayer A1c Now

Lab accurate results in 5 minutes

Package Includes: 1- self check monitor 2- single use cartridges 2- shaker kits and a quick reference guide, instructional DVD and an extra lancet

Walmart **$27.92**

To order- http://www.walmart.com/ip/Bayer-A1CNow-SelfCheck-At-Home-A1C-System-2-Test-Kit/11332213?wmlspartner=WUqD6wTpSTg&sourceid=39603268684238067687

American diabetes wholesale **23.99**

To order- http://www.americandiabeteswholesale.com/product/a1cnow-bayer-selfcheck-system_3.htm?zmam=69792428&zmas=1&zmac=63&zmap=3030&source=CJ

Medline Glucose A1C Test

0.6 mL sample size. Faster test time â€“ only 5 minutes. Unique chemistry minimizes the effects of interfering agents such as aspirin, vitamin C, uric acid, acetaminophen, providing reliable, glucose-specific results.

Med Supply.com **181.96** **Box of 10**

To order- http://www.medexsupply.com/products/pid-6389/MedlineGlucoseA1CTestBoxof10.htm?zmam=34602484&zmas=1&zmac=2&zmap=MED-DIB0310510

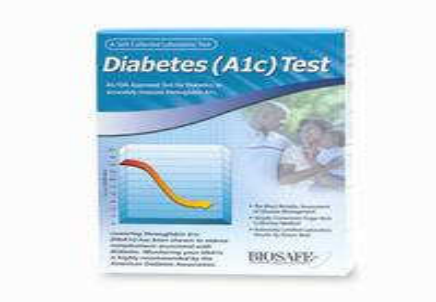
Hgb A1c Monitors

ReliOnÂ® A1c

The new ReliOnÂ® A1c test is easy to use. The mail away test provides CLIA certified laboratory results in as few as 5 days. The test result are availble by email.

Online Price $9.00

Shipping $0.97



Convenient - self-collected at home or office Accurate - Nationally Certified Laboratory results
Insurance Reimbursemant Code- included w. results

Price $19.95

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